

STATE OF HAWAII DEPARTMENT OF PUBLIC SAFETY

919 Ala Moana Boulevard, 4th Floor Honolulu, Hawaii 96814 NOLAN P. ESPINDA DIRECTOR

Maria C. Cook
Deputy Director
Administration

Jodie F. Maesaka-Hirata
Deputy Director
Corrections

Renee R. Sonobe Hong
Deputy Director
Law Enforcement

TESTIMONY ON HOUSE BILL 290, HOUSE DRAFT 1, SENATE DRAFT 1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

By Nolan P. Espinda, Director

Senate Committee on Judiciary Senator Karl Rhoads, Chair Senator Glenn Wakai, Vice Chair

Friday, March 29, 2019; 9:30 a.m. State Capitol, Conference Room 016

Chair Rhoads, Vice Chair Wakai, and Members of the Committee:

The Department of Public Safety (PSD) supports Section 1 of House Bill (HB) 290, House Draft (HD) 1, Senate Draft (SD) 1. The department, however, offers strong concerns regarding Section 2, because it is inconsistent with federal law.

PSD supports Section 1 of this measure because it proposes to permanently authorize a new controlled substance, known by the brand name "Epidiolex", as a schedule V controlled substance, which will allow for permanent public marketing in Hawaii. The controlled substance specified in this bill was scheduled by the Federal Government in 2018. This specific federal scheduling action was to include what is known as "EPIDIOLEX", a Schedule V controlled substance. As explained by Greenwich Biosciences, Epidiolex was approved by the Federal Food and Drug Administration on June 25, 2018 for the treatment of seizures associated with two rare and difficult-to-treat forms of childhood-onset epilepsy in patients two years of age and older. PSD supports only Section 1 of HB 290 HD 1 SD 1, because its passage would permanently add Epidiolex to section 329-22, HRS, to mirror recent changes to the

Testimony on HB 290, HD 1, SD 1 Senate Committee on Judiciary March 29, 2019 Page 2

federal Controlled Substances Act, thereby eliminating differences between federal and state law.

PSD, however, has strong concerns over Section 2 of this measure. Section 2 of this measure includes an additional amendment that would authorize qualifying medical cannabis patients or qualifying out of state patients to transport medical cannabis between islands for their personal use.

PSD is concerned because interisland travel through our State's airports will involve passage through many federal Transportation Security Administration (TSA) checkpoints. Those TSA checkpoints are federal enclaves where Hawaii's medical cannabis laws do not apply. Under federal law, the possession and transportation of marijuana, including medical cannabis, is not legal.

In addition, Section 2 of this measure proposes that the State Department of Transportation (DOT) and PSD create administrative rules to support the interisland transportation of medical cannabis by qualified patients. As of 2015, the administration of Hawaii's medical cannabis programs was transferred from PSD to the State Department of Health. As HB 290, HD 1, SD 1 involves issues of compliance with the DOH's medical cannabis programs, including their latest initiative to allow out of state patients to use medical cannabis in Hawaii, PSD respectfully submits that the DOH, in consultation with DOT, is the appropriate department to create the administrative rules proposed in this bill.

Thank you for the opportunity to testify on this measure.



TESTIMONY BY:

JADE T. BUTAY DIRECTOR

Deputy Directors LYNN A.S. ARAKI-REGAN DEREK J. CHOW ROSS M. HIGASHI EDWIN H. SNIFFEN

STATE OF HAWAII DEPARTMENT OF TRANSPORTATION

869 PUNCHBOWL STREET HONOLULU, HAWAII 96813-5097

March 29, 2019 9:30 a.m. State Capitol, Room 016



HB 290, H.D. 1, S.D. 1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

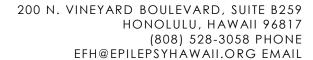
Senate Committee on Judiciary

The Department of Transportation (DOT) offers **comments** on this bill which authorizes qualifying patients or qualifying out-of-state patients to transport medical cannabis between islands for their personal medical use and directs the DOT to adopt rules pursuant to Chapter 91.

The DOT does not have jurisdiction nor the expertise to adopt rules on these matters. Possession of marijuana and cannabis infused products, such as cannabidiol oil, is illegal under federal law. Transportation Security Administration (TSA) officers are required to report any suspected violations of law, including possession of marijuana and cannabis infused products.

In the event a substance that appears to be marijuana or a cannabis infused product is observed during security screening, TSA will refer the matter to a law enforcement officer.

Thank you for the opportunity to provide testimony.





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March 27, 2019

Aloha Chair Karl Rhodes and Members of the Senate Committee on Judiciary,

I am writing in support of H.B. 290 HD1 SD1 Relating to the Uniform Controlled Substances Act along with a proposed amendment to add in language necessary to reschedule the currently FDA approved Epidiolex formula to Schedule V, in conformity with federal law. The purpose of the language is to update our state statute to make it consistent with amendments in the federal controlled substances law as required under Hawaii Revised Statutes ("HRS") section 329-11. This will allow for Epidiolex to be available to the public in the State of Hawaii.

Epidiolex was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018 for the treatment of seizures associated with Lennox Gastaux syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older. As of October 29, 2018, Epidiolex has been made available to patients in Hawaii under the Department of Public Safety's temporary rescheduling action.

Epidiolex is a Schedule V drug, the lowest DEA restriction classification, based on its low abuse potential. By adding Epidiolex to current treatment, seizures are significantly reduced in those with Dravet and LGS who were not previously helped with various epilepsy medicines. Unless Hawaii acts now individuals with Dravet and Lennox-Gastaut syndromes could experience a delay in accessing this new and innovative treatment option, a reduction in seizures, and an improved quality of life.

The Epilepsy Foundation of Hawaii is an affiliate of the Epilepsy Foundation of America and together we are the leading national voluntary health organization that speaks on behalf of the at least 14,000 individuals in Hawaii (3.4 million Americans) and their caregivers living with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services.

Mahalo for the opportunity to present this testimony. Please contact me if you have any questions.

Naomi Manuel Executive Director

Nown: Manuel

The mission of the Epilepsy Foundation of Hawaii is to lead the fight to overcome the challenges of living with epilepsy and to accelerate therapies to stop seizures, find cures, and save lives. The Epilepsy Foundation of Hawaii is an affiliate of the Epilepsy Foundation of America. It is an independent 501 (c) (3) Hawaii non-profit organization. Federal ID: 23-7216782.



To: The Honorable Karl Rhoads, Chair

The Honorable Glenn Wakai, Vice Chair

Members, Committee on Judiciary

From: Victoria Wong, MD, FAES, Medical Director, Queen's Comprehensive Epilepsy Center

and Neurodiagnostic Lab, The Queen's Medical Center

Alan Stein, MD, FAES, Physician Informaticist, Epilepsy and Neurophysiology,

Neuroscience Institute, The Queen's Medical Center

Paula Yoshioka, Vice President, Government Relations and External Affairs, The

Queen's Health Systems

Date: March 27, 2019

Hrg: Senate Committee on Judiciary Decision Making; Friday, March 29, 2019 at 9:30am in

Room 016

Re: Support for H.B. 290, H.D. 1, S.D. 1 Relating to the Uniform Controlled Substances Act

The Queen's Health Systems (Queen's) is a not-for-profit corporation that provides expanded health care capabilities to the people of Hawai'i and the Pacific Basin. Since the founding of the first Queen's hospital in 1859 by Queen Emma and King Kamehameha IV, it has been our mission to provide quality health care services in perpetuity for Native Hawaiians and all of the people of Hawai'i. Over the years, the organization has grown to four hospitals, 66 health care centers and labs, and more than 1,600 physicians statewide. As the preeminent health care system in Hawai'i, Queen's strives to provide superior patient care that is constantly advancing through education and research.

Queen's appreciates the opportunity to provide testimony in support for H.B. 290, H.D. 1, S.D. 1 Relating to the Uniform Controlled Substances Act. Under Section 1, (e), this measure would update the Hawaii Revised Statutes to be consistent with federal law and allows for continued access for our registered medical practitioners to prescribe Epidiolex to patients with epilepsy syndromes. Epidiolex is a cannabidiol oral solution currently approved by the U.S. Food and Drug Administration (FDA) for the treatment Dravet syndrome and Lennox-Gastaut syndrome, which typically do not respond to other anti-seizure medications.

Epidiolex is the first FDA-approved drug that contains a purified drug substance derived from marijuana and it is the first FDA approved drug for the treatment of patients with Dravet syndrome. Cannabidiol (CBD) is a component of marijuana but it is not a psychoactive substance meaning that the ingestion of CBD does not cause people to become intoxicated or euphoric (the "high") that comes from tetrahydrocannabinol. The Drug Enforcement Administration (DEA) has ordered that FDA-approved drugs containing "CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols" be placed in Schedule V rather than Schedule I is the most restrictive schedule and Schedule V is the least restrictive schedule of the Controlled Substances Act. This scheduling would allow registered medical

The mission of The Queen's Health Systems is to fulfill the intent of Queen Emma and King Kamehameha IV to provide in perpetuity quality health care services to improve the well-being of Native Hawaiians and all of the people of Hawai'i.



practitioners to prescribe Epidiolex. Presently in the State of Hawaii, Dr. Wong and Dr. Stein are the only practicing adult epileptologists (neurologists specializing in the care of patients with epilepsy) who have board certification in Epilepsy. The Queen's Comprehensive Epilepsy Center is the only National Association of Epilepsy Centers accredited epilepsy center in the state and we are accredited at Level 4, the highest level of accreditation. Passage of this bill would ensure that our epileptologists can continue to provide the best care possible for our community and ensure access to Epidiolex as a therapeutic option to treat Dravet syndrome and Lennox-Gastaut syndrome, both challenging forms of epilepsy. Thank you for your time and attention to this important issue.

HB-290-SD-1

Submitted on: 3/28/2019 12:23:37 AM

Testimony for JDC on 3/29/2019 9:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Carl Bergquist	Testifying for Drug Policy Forum of Hawaii	Support	No

Comments:

Chair Rhoads, Vice Chair Wakai, Committee Members:

Please pass this measure that removes the needless prohibition on interisland transportation of medical cannabis by registered patients and their caregivers.

This prohibition ties the hands of local law enforcement to whom the Transportation Security Administration (TSA) officers refer a patient apprehended with medical cannabis at one of our airports.

This kind of reform is also essential at this time as out of state medical cannabis patients, who often island-hop, are now eligible to participate in our state's medical cannabis program.

Mahalo nui.



Testimony of Jonathan Ching Government Relations Specialist

Before:

Senate Committee on Judiciary
The Honorable Karl Rhoads, Luna Hoʻomalu/Chair
The Honorable Glenn Wakai, Hope Luna Hoʻomalu/Vice Chair

March 29, 2019 9:30 a.m. Conference Room 016

Re: HB 290, HD1, SD1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

Chair Rhoads, Vice-Chair Wakai, and committee members, thank you for this opportunity to provide testimony on HB 290, HD1, SD1, which updates the Uniform Controlled Substances Act to make it consistent with amendments in federal controlled substances law as required under the authority to schedule controlled substances and authorizes qualifying patients or qualifying out-of-state patients to transport medical cannabis between islands for their personal medical use.

Kaiser Permanente Hawai'i offers the following testimony in SUPPORT of HB 290, HD1, SD1 with a proposed AMENDMENT.

We previously testified in support of SB1263 SD1, which was heard and passed out of the Senate. Section 2 of SB1263 SD1 clarifies the Uniform Controlled Substances Act (Title 21 of the Code of Federal Regulations) for electronic prescriptions by confirming that electronic prescriptions do not need to indicate quantity in *both* figures and words. This will simplify the process for these electronic prescriptions without posing the risks that quantity indications in both words and figures were intended to address when prescriptions are hand-written.

The requirement of both numeric and alphabetic quantity for prescriptions is intended to address two primary risks. First, requiring both numeric and alphabetic quantity reduces the risk of misreading quantities when the prescriber's handwriting is illegible. Second, the requirement is intended to prevent fraud by eliminating the possibility that a quantity could be increased by adding digits to a numeric quantity – e.g., turning 5 into 50 by adding 0. These issues are not present with electronic prescriptions placed in secure systems, which require multiple authentications before transmittal and cannot be modified once authenticated and transmitted. Therefore, the requirement for both numeric and alphabetic quantity in secure electronic prescriptions is not necessary.

The proposed amendments to HRS Section 329-38(i) to be consistent with the Uniform Controlled Substances Act will simplify Kaiser Permanente Hawai'i's electronic prescription process without exposing our patients to any increased risk of error or fraud.

We respectfully urge the committee to support this language and amend HB 290, HD1, SD1 to add in the language from Section 2 of SB 1263, SD1 (see below).

Thank you for the opportunity to provide testimony on this important measure.

LANGUAGE TO BE ADDED:

- SECTION 2. Section 329-38, Hawaii Revised Statutes, is amended by amending subsection (i) to read as follows:
- "(i) Prescriptions for controlled substances shall be issued only as follows:
- (1) All prescriptions for controlled substances shall originate from within the State and be dated as of, and signed on, the day when the prescriptions were issued and shall contain:
 - (A) The first and last name and address of the patient; and
 - (B) The drug name, strength, dosage form, quantity prescribed, and directions for use. Where a prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.

Except for electronic prescriptions, controlled substance prescriptions shall be no larger than eight and one-half inches by eleven inches and no smaller than three inches by four inches. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to indicate the amount of controlled substance to be dispensed. Where an electronic prescription is permitted, either words or figures (e.g., alphabetically or numerically as indications of quantity, such as five or 5), to indicate the amount of controlled substance to be dispensed shall be acceptable. Where an oral order or electronic prescription is not permitted, prescriptions shall be

written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address, telephone number, and registration number of the practitioner. prescriptions may be prepared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner shall be responsible in case the prescription does not conform in all essential respects to this chapter and any rules adopted pursuant to this chapter. In receiving an oral prescription from a practitioner, a pharmacist shall promptly reduce the oral prescription to writing, which shall include the following information: the drug name, strength, dosage form, quantity prescribed in figures only, and directions for use; the date the oral prescription was received; the full name, Drug Enforcement Administration registration number, and oral code number of the practitioner; and the name and address of the person for whom the controlled substance was prescribed or the name of the owner of the animal for which the controlled substance was prescribed.

A corresponding liability shall rest upon a pharmacist who fills a prescription not prepared in the form prescribed by this section. A pharmacist may add a patient's missing address or change a patient's address on all controlled substance prescriptions after verifying the patient's identification and noting the identification number on the back of the prescription document on file. The pharmacist shall not make changes to the patient's name, the controlled substance being prescribed, the quantity of the prescription, the practitioner's Drug Enforcement Administration number, the practitioner's name, the practitioner's electronic signature, or the practitioner's signature;

(2) An intern, resident, or foreign-trained physician, or a physician on the staff of a Department of Veterans Affairs facility or other facility serving veterans, exempted from registration under this chapter, shall include on all prescriptions issued by the physician:

- (A) The registration number of the hospital or other institution: and
- (B) The special internal code number assigned to the physician by the hospital or other institution in lieu of the registration number of the practitioner required by this section.

The hospital or other institution shall forward a copy of this special internal code number list to the department as often as necessary to update the department with any additions or deletions. Failure to comply with this paragraph shall result in the suspension of that facility's privilege to fill controlled substance prescriptions at pharmacies outside of the hospital or other institution. Each written prescription shall have the name of the physician stamped, typed, or hand-printed on it, as well as the signature of the physician;

- (3) An official exempted from registration shall include on all prescriptions issued by the official:
 - (A) The official's branch of service or agency (e.g., "U.S. Army" or "Public Health Service"); and
 - (B) The official's service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee shall be the employee's social security or other government issued identification number.

Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer; and

(4) A physician assistant registered to prescribe controlled substances under the authorization of a supervising physician shall include on all controlled substance prescriptions issued:

- (A) The Drug Enforcement Administration registration number of the supervising physician; and
- (B) The Drug Enforcement Administration registration number of the physician assistant.

Each written controlled substance prescription issued shall include the printed, stamped, typed, or hand-printed name, address, and phone number of both the supervising physician and physician assistant, and shall be signed by the physician assistant. The medical record of each written controlled substance prescription issued by a physician assistant shall be reviewed and initialed by the physician assistant's supervising physician within seven working days."

TESTIMONY OF NAHELANI WEBSTER ON BEHALF OF GREENWICH BIOSCIENCES

To: Chair Rhoads and Members of the Senate Judiciary Committee.

Date: Friday, March 29, 2019 at 9:30AM in conference room 016.

Re: Support for H.B. 290 HD1 SD1

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences (GW) in **support of H.B. 290 HD1 SD1** Relating to the Uniform Controlled Substances Act, Section 1 only.

The purpose of this bill is to update our state statute to make it consistent with amendments in the federal controlled substances law as required under Hawaii Revised Statutes ("HRS") section 329-11. This will allow for Epidiolex to be available to the public in the State of Hawaii.

Epidiolex was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018 for the treatment of seizures associated with Lennox Gastaux syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older. Epidiolex is a Schedule V drug, the lowest DEA restriction classification, based on its low abuse potential.

This measure would add specific language to HRS § 329-22, which is an extremely narrow formula, only applicable to Epidiolex. **This does <u>not</u> impact nor apply to any other forms of cannabidiol products.** This specific formula also requires FDA approval.

By adding Epidiolex to current treatment, seizures were significantly reduced in those with Dravet and LGS who were not previously helped by other epilepsy medicines. Since the temporary rescheduling of Epidolex in the State of Hawaii, patients have been receiving Epidiolex. Not passing this language would result in patients losing out on an important option for their treatment.

GW is always seeking solutions that will transform lives, and this is why they continue to advance cannabinoid science and study new medications to help meet serious unmet patient and caregiver needs. For GW, Epidiolex is just the first step towards transforming the treatment of epilepsy in one's lifetime.

Thank you for the opportunity to present this testimony. Please contact me if you have any questions.





HAWAII EDUCATIONAL ASSOCIATION FOR LICENSED THERAPEUTIC HEALTHCARE

To: Senator Karl Rhoads, Chair

Senator Glenn Wakai, Vice-Chair

Members of the Senate Judiciary Committee

Fr: Blake Oshiro, Esq. on behalf of the HEALTH Association

Re: Support – HB290 HD1 SD1 Relating to the Uniform Controlled Substances Act

Dear Chair Rhoads, Vice-Chair Wakai, and Members of the Committee:

HEALTH is the trade association made up of the eight (8) licensed medical cannabis dispensaries under Haw. Rev. Stat. (HRS) Chapter 329D. We **support SECTION 2 of HB290 HD1 SD1 dealing with intrastate or interisland transport.** We appreciate the committee's willingness to move this measure.

While we recognize that any state law does not change the federal law and enforcement when it comes to transport of cannabis <u>inter</u>state, it is our understanding that a state law can assist in providing guidance and clarity for some enforcement in commercial carrier settings <u>intra</u>state. This is because the law on transport INTRASTATE appears to be uncertain. There is an existing rule that MAY permit transport when there is also a state law authorizing such transport. The 1972 Federal Aviation Administration (FAA) rule that bans pilots from operating aircraft with illegal substances on board specifies that it "does not apply to any . . .marihuana, . . . authorized by or under any Federal or State statute or by any Federal or State agency."

Cubrant A Canaral

Subpart A—General

§91.19 Carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances.

(a) Except as provided in paragraph (b) of this SECTION, no person may operate a civil aircraft within the United States with knowledge that narcotic drugs, marihuana, and depressant or stimulant drugs or substances as defined in Federal or State statutes are carried in the aircraft.

(b) Paragraph (a) of this SECTION does not apply to any carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances authorized by or under any Federal or State statute or by any Federal or State agency.

¹ Title 14: Aeronautics and Space PART 91—GENERAL OPERATING AND FLIGHT RULES



The Voice of Hawai'i's Licensed Medical Cannabis Dispensaries

Thus, the adoption of this language into law would provide some necessary protection and clarification on the state's position, and some further support for dispensaries to be able to transport medical cannabis under these limited circumstances.

Thank you for your consideration.